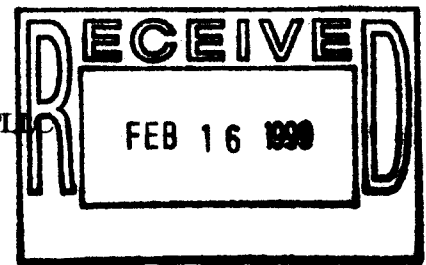


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February 11, 1999

Dr. C.W. Jameson
National Toxicology Program
Report on Carcinogens
79 Alexander Drive Room 3217
P.O. Box 12233
Research Triangle Park, NC 27709

Dear Dr. C.W. Jameson:

Footwear Industries of America, Inc. ("FIA") is pleased to have the opportunity to comment on the National Toxicology Program's ("NTP's") Board of Scientific Counselors' recommendation to defer listing the boot and shoe manufacture and repair industry in its Report on Carcinogens, Ninth Edition ("Ninth Report"). 63 *Fed. Reg.* 68,783 (1998). FIA is the national trade association that represents manufacturers and distributors of nonrubber footwear and their suppliers. As such, NTP's references to the boot and shoe industry in its reports have a direct impact on FIA member companies.

I. FIA Supports NTP's Decision to Defer Listing the Boot and Shoe Industry in its Ninth Report Due to Insufficient Data.

NTP's Board of Scientific Counselors has proposed to defer listing the boot and shoe industry in its Ninth Report based on the lack of adequate data on exposure assessment. FIA commends NTP for recognizing that it does not have sufficient information upon which to base a decision to list the industry in its Report. FIA fully supports this decision.

Although the *Federal Register* notice did not indicate the practical import of such a deferral, FIA assumes that NTP will not make *any* reference to the footwear industry in the Report. If NTP does not have sufficient data to *list* the industry, it certainly does not have a reasonable basis for *referencing* the industry, even if such references are limited to remarks in the introduction or the appendix. To cite shoe manufacturing as an industry posing an occupational exposure risk while

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simultaneously acknowledging that there is insufficient evidence to assess risk exposures to U.S. workers would certainly be ill-advised. Accordingly, FIA strongly urges that NTP defer *referencing* the boot and shoe industry in any way in the upcoming Ninth Report on Carcinogens.

II. Scientific and Technical Data on Occupational Exposures in the Industry Do Not Support Referencing the Boot and Shoe Industry.

On numerous occasions, including the December 1998 meeting of the Board of Scientific Counselors, FIA has provided testimony and extensive submissions demonstrating the lack of scientific justification for citing the footwear industry in NTP's Reports on Carcinogens. Rather than reiterating FIA's previous statements, we have attached a copy of the testimony provided by Ralph Mosely on behalf of FIA at the December meeting. See Attachment 1 (Comments from FIA Regarding Whether Boot and Shoe Manufacturing and Repair Should Be Referenced in the Ninth Biennial Report on Carcinogens, November 25, 1998).

In sum, Mr. Mosely's testimony demonstrates that the data upon which NTP has relied to include the boot and shoe industry in past editions of the Report on Carcinogens is an inappropriate basis for making a listing decision. First, the data is old and outdated. Even NTP's 1998 Background Document on the footwear industry recognized that many of the agents assessed in the studies relied on by NTP are no longer (or never were) used in the U.S. footwear industry. Second, most of these studies focused on footwear producers in foreign countries that used chemicals and/or processes that are no longer (or never were) used in the U.S. footwear industry.

Additionally, "dose" and "response" data, upon which almost all human toxicology studies are based, do not provide a basis to list or reference the boot and shoe industry. "Dose" data addresses the concentration of a particular chemical to which workers are exposed. The studies of domestic footwear companies demonstrate that the chemical exposures to workers were well within OSHA's permissible exposure limits and, most of the time, were even within NIOSH's voluntary recommended exposure limits. Accordingly, the chemical dose being received by American workers in the footwear industry is generally within mandatory and voluntary limits, and cannot reasonably be used as a justification for citing the footwear industry in the NTP Reports.

Nor is a listing supported by available "response" data, which is generated from epidemiology studies. As more fully addressed in Mr. Mosely's testimony (*see* Attachment 1), all of the studies conducted in the United States concern employees whose work exposures ranged from the 1940s to the 1960s, with a few data points in the 1970s. Even the "current" epidemiologic study that was conducted by Walker, *et al.*, in 1993 actually concerned workers in two Ohio factories whose employment histories ran from 1940 to 1979. These studies are simply too old and outdated to provide sound epidemiologic "response" data.

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Finally, NTP should note that even the outdated data do not provide clear evidence of a death rate due to one single occupational cause or exposure within the boot and shoe industry.

III. NTP Lacks Legal Authority to Cite the Boot and Shoe Industry in its Report.

As FIA has repeatedly advised NTP, there is no statutory authority to list: (1) industrial classifications, as opposed to substances, in general; and (2) the boot and shoe industry, in particular. See Attachment 2 (Comments of FIA on the Eighth Biennial Report on Carcinogens, November 12, 1996).

To summarize, NTP's statutory authority under the Public Health Service Act is limited to listing chemical substances, as opposed to industrial occupations, in its reports. 42 U.S.C. § 241(b)(4)(A). If NTP identifies a chemical substance used in an industry that poses or may pose a carcinogenic risk, it should list the substance, *not the entire industry*. Here, NTP concedes that it has not -- and cannot -- identify a single chemical substance used in the domestic footwear industry that poses a carcinogenic risk. The agency has thereby simply ignored its statutory mandate. Moreover, by side-stepping the Congressional directive to identify a specific substance that poses a carcinogenic risk, the agency has denied the footwear industry the procedural safeguards applicable to "listed" chemical substances, which ensure that a listing is based on current and reliable data. References to the footwear industry in the NTP's reports are thus legally flawed.

Second, even if the agency had the legal authority to spotlight entire industrial processes, the statute authorizes NTP to include a listing only where a "significant number of persons residing in the United States are exposed." 42 U.S.C. § 241(b)(4)(A). However, the data that NTP has historically used to justify its references to the footwear industry is indisputably data demonstrating potential risk to foreign employees. Under the Public Health Service Act, these risks -- even if legitimate -- cannot be relied on to drive agency action affecting U.S. companies and their workers.

IV. Conclusion

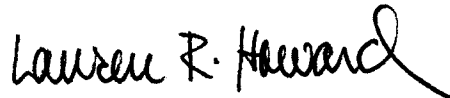
FIA's member companies will be irreparably harmed if the National Toxicology Program references the boot and shoe industry anywhere in the Ninth Report on Carcinogens, including the introduction or the appendix. As NTP is aware, many federal and state health, safety, and environmental initiatives are launched because of the findings in NTP's biennial reports. Additionally, liability insurance and toxic tort lawsuits are driven, at least in part, by NTP's pronouncements.

Because of the harm that could result from a reference in the Report, it is critical that NTP have a sound basis to support its decision. There is simply no evidence of a correlation between cancer and occupational exposures in the modern boot and shoe industry in the United States. FIA believes the relevant data unquestionably demonstrates that references to footwear manufacturing

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should be permanently removed from NTP's Reports altogether. Short of this, however, the National Toxicology Program should defer action on this industry. Since the Board of Scientific Counselors has properly acknowledged that it does not have sufficient data to justify the listing of the boot and shoe industry in the upcoming Report, the NTP should refrain in the interim from making any reference in the Ninth Report that would unfairly and unlawfully tarnish this industry.

Very truly yours,

A handwritten signature in black ink, reading "Lauren R. Howard". The signature is fluid and cursive, with the first name "Lauren" and last name "Howard" clearly legible.

Lauren R. Howard
Kathryn M.T. McMahon
Counsel to Footwear Industries of America, Inc.

Attachments

COMMENTS OF FOOTWEAR INDUSTRIES OF AMERICA, INC.
ON THE LEGALITY OF
LISTING BOOT AND SHOE MANUFACTURE AND REPAIR IN
THE NINTH REPORT ON CARCINOGENS

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November 24, 1998

INTRODUCTION

Footwear Industries of America, Inc. ("FIA") is the national trade association representing manufacturers and distributors of nonrubber footwear and their suppliers. FIA opposes listing or referencing the boot and shoe manufacture and repair industry in the National Toxicology Program's Ninth Report on Carcinogens ("BRC" or "Report"). To do so would directly contravene NTP's legal authority to list chemical substances in the Report. 42 U.S.C. § 241(b)(4)(A). For the reasons set forth below, we urge you to determine that it is inappropriate to refer anywhere in the Ninth Report to boot and shoe manufacture and repair.

A. NTP Lacks Statutory Authority To List Occupational Exposure Circumstances In The BRC

Under the 1993 amendments to the Public Health Service Act, the Secretary of the Department of Health and Human Services ("the Secretary") is required to publish an annual report which contains a list of all substances that are known, or reasonably suspected, to be carcinogens to which a significant number of persons residing in the United States are exposed. 42 U.S.C. § 241(b)(4)(A). There is no legal basis to support NTP's proposal to list "exposure circumstances" in the Report. In fact, NTP has expressly stated that manufacturing processes "do not qualify for formal review for BRC listing because no specific agent, substance or mixture has been identified with the exposures involved." 61 Fed. Reg. 55,165 (1996) (emphasis added). Listing "exposure circumstances" in the Report is therefore in direct contravention of NTP's statutory authority to list only substances, a fact conceded by NTP.

At most, the statute permits inclusion of information concerning the nature of an exposure to one of the specific substances listed in the Report. See 42 U.S.C. §241(b)(4)(B). However, even

assuming that industries could properly be listed in this context, the monographs prepared by the International Agency for Research on Cancer ("IARC"), upon which the Report relies, make no attempt to link footwear manufacturing to any listed substance, with the sole exception of benzene -- a substance that has not been used in the manufacture of shoes in the United States for more than 25 years. IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Vol. 25, Table 2, 262 (1981) ("Monograph Vol. 25"). In fact, the IARC research only suggests a possible link to cancer from leather dust, a "substance" that is not listed as a carcinogen in the Report. *Id.* at 274.

It is clear that "boot and shoe manufacture and repair" is not a "substance" within the meaning of the statute. It is equally clear that the listing of boot and shoe manufacture and repair does not in any way provide information concerning the nature of exposures to any of the specific substances identified in the Report. Therefore, the Secretary has no authority to include references to the boot and shoe manufacturing and repair industries in any section of the Ninth BRC.

B. NTP Lacks Statutory Authority to Include A Substance In The BRC Unless A "Significant Number of Persons Residing In the United States Are Exposed"

Even if NTP had authority to list occupational exposures in addition to substances -- which clearly it does not -- the Public Health Service Act further limits NTP's authority to include in the annual reports only those occupational exposures to which a "significant number of persons residing in the United States" are exposed. 42 U.S.C. § 241(b)(4)(A). This statutory provision clearly and explicitly mandates that NTP not list substances (or occupational exposures) simply because they may pose a carcinogenic risk to persons in other countries. However, as detailed below, and in comments submitted by Ralph Mosely, the studies upon which NTP has relied to list or reference

the boot and shoe industry are virtually exclusively studies of manufacturing operations in *other* countries. See section B, *infra*. Comments of Ralph E. Mosely, November 30, 1998. Accordingly, because no credible evidence of increased incidences of cancer caused by occupational exposures in U.S. manufacturing or repair facilities exist, NTP does not have statutory authority to list the boot and shoe industry in its Ninth Report.

C. There Is No Scientific Basis for Listing the Footwear Industry

The statute authorizing the Secretary to issue the BRC requires that a credible scientific basis exist before a substance can be listed. 42 U.S.C. §241(b)(4)(A). The legislative history of the statute explains that the phrase "'suspected carcinogens' [was replaced] with 'substances. . . reasonably anticipated to be carcinogens,' in order to make it absolutely clear in the statute that there must be reasonable ground for designating a substance as a putative carcinogen." Joint House-Senate Summary and Explanation (Oct. 14, 1978) as reprinted in 1978 U.S.C.C.A.N. 9063, 9080.

However, there is no credible scientific evidence in the outdated and inconclusive IARC studies on which NTP relies to justify the listing of the footwear industry in the upcoming BRC. Comments of Ralph E. Mosely on Behalf of Footwear Industries of America, Inc. on the Ninth Biennial Report on Carcinogens ("Comments of Ralph Mosely"). In particular, the studies of shoemaking in other (often third-world) countries do not fairly describe the conditions in the technologically advanced operations of American shoe manufacture today.

Modern U.S. boot and shoe manufacturing facilities are marked by: (1) pervasive government occupational health regulations; (2) a high degree of automation resulting in the removal of workers from many areas of exposure that existed in the older processes; and (3) a reduction or elimination of the use of certain materials and chemicals that are most suspected of being

carcinogens. IARC did not account for these changes in rendering its determination that boot and shoe manufacture and repair is a process associated with increased incidence of cancer. Comments of Ralph Mosely, November 30, 1998..

When FIA alerted NTP to these problems with the IARC research in 1986, the Fourth Annual Report on Carcinogens deleted the reference to boot and shoe manufacturing repair in the section of the Report identifying technological processes known to be carcinogenic. NTP retained only a brief reference to boot and shoe manufacturing in the Introduction to the BRC, but included several disclaimers, including the following:

- (1) Manufacturing processes "vary significantly" in different countries;
- (2) Manufacturing processes have changed significantly over the last few years; and
- (3) There is a great likelihood of variation in exposures to the cause of cancers.

National Toxicology Program. Fourth Annual Report on Carcinogens at 10.

Because of the lack of valid and credible data justifying the identification of the entire U.S. boot and shoe manufacturing industry as carcinogenic, there is insufficient scientific basis for listing boot and shoe manufacture and repair in the Ninth BRC.

CONCLUSION

Footwear Industries of America, Inc. urges the National Toxicology Program not to list boot and shoe manufacture and repair in the Ninth Biennial Report on Carcinogens. The unwarranted identification of boot and shoe manufacture as an exposure circumstance linked to increased incidence of cancer creates the potential for increased regulation, given that many federal and state health initiatives are launched from NTP findings. In addition, American shoe companies could be faced with unjustified increases in insurance and legal costs.

Such problems would clearly be hard for this beleaguered industry to bear. Imports increased from 175 million pairs in 1968 to more than 1 billion pairs in 1996, capturing more than 90 percent of the U.S. market in that year. With this loss of all but a small share of domestic consumption, U.S. production declined from 642 million pairs in 1968 to less than 150,000 pairs in 1996. As a result, there has been a net loss of more than 230 factories and more than 40,000 jobs in the past decade alone. At the end of 1996, only 45,000 workers still produced nonrubber footwear in this country.

Considering the potentially serious consequences of NTP's decision to list boot and shoe manufacture and repair in this Report, statutory authority and substantial scientific evidence should be required before this entire industry is labeled carcinogenic.